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SONNENSCHEIN NATH & ROSENTHAL LLP
P.O. BOX 061080
WACKER DRIVE STATION, SEARS TOWER
CHICAGO, IL 60606-1080

EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/766,227	THEUER, RICHARD C.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-43* is/are rejected.

7)☒ Claim(s) *1, 3, 5, 12, 20, 27, 32* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-43 are pending.

Information Disclosure Statement

1. The information disclosure statement filed June 17, 2004 has been considered.

Claim Objections

2. Claims 1, 3, 5, 12, 20, 27, 32 are objected to because of the following informalities:

- Claim 1 should have a period at the end of the sentence.
- Claim 3 depends from claim 5; a claim should depend from a prior claim, not a later number claim.
- Claims 5 and 12 recite improper Markush format. A Markush claim should recite the phrase "selected from the group consisting of" and list the species separated by commas A, B, and C; and not A, B and C and D (claims 5, 20, 32); nor A, B or C or D (claims 12 and 27). Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 3 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 depends from claim 5 and is directed to specific specie of H2 receptor antagonists, while claim 5 is directed to proton pump inhibitors; the species recited in claim 3 are not further limiting of claim 5 and lack antecedent basis in claim 5. Claim 3 should depend from claim 2 to clearly claim the invention.

Claim 5 depends from claim 4 and recites a Markush group of species of proton pump inhibitor, while claim 4 only recites species of 2-pyridylmethylsulfinylbenzimidzole compounds. The species recited in claim 5 that are not 2-pyridylmethylsulfinylbenzimidzole compounds lack antecedent basis in claim 4 from which it depends. All pyridylmethylsulfinylbenzimidzole compounds are not 2-pyridylmethylsulfinylbenzimidzole compounds especially when claim 5 is directed to derivatives of the recited compounds. Claim 5 is also objected to as not being further limiting of claim 4 from which it depends for the above-recited reasons defined by lack of antecedent basis. Claim 5 should depend from claim 2.

Please Note: the following prior art rejections are being applied against the claims in light of the definitions provided in the instant Specification paragraphs [008-0022] and the species recited in the claims.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 1-5, and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 2349570 Dettmar et al.

Instant claims 17-20: Dettmar et al disclose the instantly claimed oral dosage formulation (see page 29, claim 13, "mouth, throat, pharynx and/or stomach") compositions that comprise the combination of a:

- vitamin (choline (Instant Specification defined at page 5, [0015] and GB 2340570, page 10, line 30 and abstract) together with
- an antacid (ant ulcer agent which is a histamine H2 receptor antagonist, proton pump inhibitor or antacid: see GB'570, page 11, lines 6-13).

Instant claims 1-5: The oral formulations are administered to a patient in a method of treating a patient, the method comprising the step of:

Administering one or more substances that neutralize or other wise reduce gastric acid (see GB '570, page 11, lines 6-13) together with an effective amount (see GB'570, page 14, lines 25-27) supplemental amount of a vitamin (see GB'570, page 10, line 30) choline.

Dettmar et al anticipates the instantly claimed invention.

7. Claims 1-9, 11-12, 16, 17-24, 26-27 a re rejected under 35 U.S.C. 102(b) as being anticipated by Fuiz (US Pat. 5,518,730, issue date May 21, 1996).

Instant claims 17-24, 26-27: Fuiz disclose the instantly claimed oral dosage formulation (see col. 15, claim 7) compositions that comprise the combination of a:

- vitamin (ascorbic acid (Fuiz, col. 8, line 7; claim 26-27 "vitamins"), choline, biotin, cyanocobalamin (free B12), folic acid, inositol, riboflavin, vitamin A, vitamin B,

vitamin C, vitamin D, vitamin E, and vitamin K (Fuiz, claims 5, 19 and 26-27; Fuiz Specification, col. 7, line 67 "mixtures of these agents") together with

- an antacid (see col. 7, line 44; calcium carbonate, calcium, sodium bicarbonate (see Fuiz col. 16, line 52) and cimetidine (col. 16, line 58) and ranitidine (col. 17, lines 37-38), which are histamine H2 receptor antagonist. And/or omperazole, a proton pump inhibitor (see col. 8, line 54, Fuiz claims 5 and 19)

Instant claims 1-9, 11-12, and 16: The oral formulations are administered to a patient in a method of treating a human (see col. 4, line 5 and line49) patient, the method comprising the step of:

Administering one or more substances that neutralize or other wise reduce gastric acid (see col. 7, lines 44, 64, and 67 "mixtures"; col. 14, claim 5 "calcium carbonate"; claims 5 and 19 ""cimetidine" and ranitidine" , col. 8, line 54 "omeprazole") together with an effective amount of a supplemental amount of a vitamin (see col. 14 and 16, claims 5 and 19, biotin, choline, cyanocobalamin, folic acid, inositol, riboflavin, vitamin A, vitamin B, vitamin C, vitamin D, vitamin E, and vitamin k) in a single oral dosage form (see col. 9, lines 13-19 "oral forms such as tablets, capsules, beads, granules, aggregates, syrups, powders, gels, solids, semi-solids, suspensions and liquids").

Instant claims 29-34, 36-40: Fuisz discloses a method of making an oral dosage formulation that comprises the step of :

- Applying a coating ("if the dosage is to be administered orally, the polymer must provide a protective barrier against fluids" , which is a "non-saccharide biodegradable polymer (see claim 1) united with bio-effecting agent formed by flash-flow melt-spin processing) the dosage form with a protective barrier covering, the dosage form being free vitamin B12 (see col. 14, line 63, claim 5 "cyanocobalamin"; also see col. 16, line 62 "cyanocobalamin"), and vitamin C (see ascorbic acid, col. 8, line 7; claims 5 and 19) , together with one or more substances that neutralize or otherwise reduce gastric acid (see claims 5 and 19 and 22, "calcium carbonate,

calcium, sodium bicarbonate, cimetidine, ranitidine, and omeprazole). Fuisz anticipates the instantly claimed invention.

8. Claims 1-2, 4-7, 10, 14-16 (method of treating), 17-18 20-22, 25, (formulations), 29, 30, 32, 35-39 (method of making) are rejected under 35 U.S.C. 102(e or a) as being anticipated by Abrams et al (US Pat. 6,428,809).

Instant claims 17, 18, 20-22, 25 :Abrams et al disclose the instantly claimed compositions of claims 17, 20-22 and 25 that comprise:

- an oral dosage formulation (see col. 1, line 67) ,
- the formulation comprising a substance to reduce gastric acid (omeprazole, see col. 6, line 34; col. 7, line 11) together with
- one or more vitamins (see col. 6, lines 34-35 (vitamin B12), wherein
  - the dosage of vitamin B12 is from 25 micrograms to 1 milligram (see col. 6, line 35).

Abrams et al anticipate the instantly claimed oral formulations.

Instant claims 1, 2, 4-7, 10: Abrams et al disclose a method of treating a human patient (see col. 1, lines 36-37 "patient compliance"), the method comprising the step of:

Administering (see col. 1, lines 65-67 "administered") a therapeutically effective amount (see col. 7, line 7, "improve therapeutic response") of a substance to reduce gastric acid (See col. 7, line "omperazole is an inhibitor of gastric secretion") and administering an effective amount of a vitamin (Vitamin B12 "eliminate the potential problems", col. 7, lines 10-15).

Instant claim 14: The administered formulation is provided in a first oral dosage form and a second dosage form (see col. 6, lines 53-54).

Instant claim 15: wherein the first oral dosage form and second dosage form are packaged together in a unit-dose packaging (see col. 6, lines 40-65).

Instant claim 16: wherein the administered formulation is a single oral dosage form (see col. 6, line 51).

Instant claims 29-30, 32, 35: Abrams et al disclose the instantly claimed method of making an oral dosage form, the method comprising the step of:

Applying a coating (see col. 6, line 65; col. 6, line 15 "covered by an acid or alkaline dissolvable protective membrane"; see claim 8) comprising free Vitamin B 12 (see col. 6, lines 33-65) to a pharmaceutical preparation of a substance that reduces gastric acid (omperazole, col. 6, line29-30) in a dosage form (see col. 6, lines 34-35).

Instant claim 36: The preparation is a tablet (see col. 6, line 8)

Instant claim 37: enterically coated tablet (see col. 5, lines 50-60 "dissolvable material" to release in the stomach or intestine).

Instant claim 38: film coated ("laminates of polymeric material" col. 2, lines 27-29; polymeric capsules , col. 2, line 23; col. 5, lines 3-4"powdered medicine sandwiched between semi permeable or permeable membranes" figure 1).

Instant claim 39: capsule (see col. 3, line 4 "gelatin capsule for oral dosage"; col. 6, line 64 "placed in a capsule" Figure 7). Abrams et al anticipates the instantly claimed invention as now claimed.

9. Claims 1-2, 6-7, 8-13(method of treating), 17-18, 21-23, 25-28 (formulations), 29, 30, 33-40, 42-43 (method of making) are rejected under 35 U.S.C. 102(e) as being anticipated by Giordano et al (PG-Pub 2004/0166175, effective filing date December 10, 2002).

Instant claims 17-18, 21-23, 25-28: Giordano et al disclose the instantly claimed compositions that comprise:

- an oral dosage formulation, that may be coated or enteric coated (see page 7, [0051] (see page 6, [0050]) , in a single dosage form or multiple dosage compositions that may be co-administered see page 6 [0049])

  the formulation comprising a substance to reduce gastric acid (magnesium, calcium, see page 8, claim 1) together with

- one or more vitamins (see claims 1-186, especially claims 15, 30, 21,30 46, (vitamin B12 and vitamin C), wherein

- the dosage of vitamin B12 is from 10.8 micrograms to 13.2 milligram (see page 8, claim 36; also see page 4-5 [0038 "cobalamin" "cyanocobalamin, methylcobalamin, hydroxocobalamin, adenosylcobalamin and hydroxycyanocobalamin")
- the dosage of vitamin C is from 63 mg to 77 mg (see page 3, [0029-0031 "ascorbic acid").

Giordano et al anticipate the instantly claimed oral formulations.

Instant claims 1-2, 6-7, 8-16: Giordano et al disclose a method of treating a human patient (see page 3, [0022]), the method comprising the step of:

Administering (see page 6 [0050], page 9, claims 94-96) a therapeutically effective amount of a substance to reduce gastric acid (See magnesium, calcium are species of antacid; claim 1, page 8) and administering an effective amount of a vitamin (Vitamin B12, vitamin C, see pages 9-10, claim 94, claim 108, claim 114) in a single dosage or combination of first and second dosage forms (see page 6, [0049-0050]

Instant claims 29, 30, 33-35, 42-43: Giordano et al disclose the instantly claimed method of making an oral dosage form, the method comprising the step of:

Applying a coating (see page 7, [0051] "sugar coated or enteric coated by standard techniques") comprising free Vitamin B 12 to a pharmaceutical preparation of a substance that reduces gastric acid in a dosage form (see all claims, and Example 1), specifically calcium and magnesium which serve as antacids.

Instant claim 36: The preparation is a tablet (see page 7, [0051 "tablets"]).

Instant claim 37, 42: enterically coated tablet (see page 7, [0051 "enteric coated"]).

Instant claim 38, 43: film coated (see page 7, [0051, "sugar coated", a type of film; page 6, [0049, caplets or capsules, a type of film coating/carrier] and [0051 "disintegrating agents and the like", page 6, col. 2, last line]).

Instant claim 39: capsule (see page 6, [0049 line 3 "capsules").

Instant claim 40: wherein the one or more vitamins comprises vitamin C (see all claims and pages 3-4, paragraphs [0029-0031]). Giordano et al anticipates the instantly claimed invention as now claimed.

1. Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

2. Inherently the reference anticipates the now claimed invention. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. The Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

10. Claim 41 is rejected under 35 U.S.C. 102(e) as being anticipated by Hermelin (US PG-Pub 2004/0062802, effective filing date December 30, 1999).

Hermelin discloses the instantly claimed invention directed to a method of making an oral dosage formulation, wherein the oral dosage formulation is chewable tablets, quick dissolve tables, capsules to name a few (see claim 51, page 22, first half of claim), the method comprising the step of:

Making [see paragraph 0099, "formulated for administration" and paragraph [0144]-0160 "mixing", "extruding", "dispersing"]

a tablet (see page 22, claim 51 depends from claim 1, "Tablet")

comprising free Vitamin B12 (see page 21, claim 39 depends from claim 1, "cyanocobalamin") ,

Vitamin C (see page 21, claim 39 depends from claim 1, "ascorbic acid") and

one or more proton pump inhibitors (see page 21, claims 11 and 14 which depend from claim 1, "omeprazole, lansoprazole, and combinations thereof").

The reference anticipates the instantly claimed method of making an oral dosage formulation.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US006051570A US006852739B1 US006500459B1 US006391294B1 US006863904B2 US 20030012826A1 US 20020107265A1 US 20030108624A1 US 20020197317A1 US 20030215496A1 US 20040052824A1 US 20040058012A1 US 20020197330A1 US 20040086574A1 US 20050079216A1 US 20020137771A1 4,508,905; 4,255,431; 4,337,257; 6,391,332; 6,660,293; 6,702,683; 20010031744; 20020015742; 20020061835; 20040109901 and 20040142036 are cited to show compositions that comprise a vitamin together with a substance that will neutralize or reduce gastric acid.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
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LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600